

**UNITED STATES DISTRICT COURT  
MIDDLE DISTRICT OF NORTH CAROLINA**

NATHAN SILVA, Derivatively on Behalf of  
Nominal Defendant HUMACYTE, INC.,

Plaintiff,

v.

KATHLEEN SEBELIUS, EMERY N.  
BROWN, MICHAEL T. CONSTANTINO,  
BRADY W. DOUGAN, C. BRUCE  
GREEN, LAURA E. NIKLASON, TODD  
M. POPE, DIANE SEIMETZ, MAX  
WALLACE, SUSAN WINDHAM-  
BANNISTER, DALE A. SANDER,  
HEATHER PRICHARD, and AYABUDGE  
LLC

Defendants,

and

HUMACYTE, INC.,

Nominal Defendant.

Case No. 1:25-cv-5

**DEMAND FOR JURY TRIAL**

**VERIFIED SHAREHOLDER DERIVATIVE COMPLAINT**

Plaintiff Nathan Silva (“Plaintiff”), by and through his undersigned attorneys, brings this derivative complaint for the benefit of nominal defendant Humacyte, Inc. (“Humacyte” or the “Company”), against certain current and former members of the Company’s Board of Directors (the “Board”) and certain of its executive officers seeking to remedy the Individual Defendants’ (defined below) breaches of fiduciary duties and violations of federal law. Plaintiff alleges the following based upon personal knowledge as to himself and his own acts, and information and belief as to all other matters, based upon, *inter alia*, the investigation conducted by and through Plaintiff’s attorneys, which included, among other things, a review of Defendants’ publicly available documents, United States Securities and Exchange Commission (“SEC”) filings, press releases published by and regarding Humacyte, legal filings, news reports, securities analysts’ reports about the Company, and other publicly available information.

### **NATURE OF THE ACTION**

1. This is a shareholder derivative action brought by Plaintiff on behalf of Humacyte against certain of its officers and current and former members of the Board (the “Individual Defendants”)<sup>1</sup> for breaching their fiduciary duties by consciously, intentionally, and/or recklessly allowing the Company to operate without sufficient controls and in blatant and obvious violation of the law, including federal securities laws.

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<sup>1</sup> The Individual Defendants are Kathleen Sebelius, Emery N. Brown, Michael T. Constantino, Brady W. Dougan, C. Bruce Green, Laura E. Niklason, Todd M. Pope, Diane Seimetz, Max Wallace, Susan Windham-Bannister, Dale A. Sander, Heather Prichard, and Ayabudge LLC, who are sometimes referred to herein by their last names. “Defendants” means Humacyte and the Individual Defendants.

2. Between at least April 29, 2024 and October 17, 2024 (the “Relevant Period”), the Individual Defendants intentionally and/or recklessly allowed the dissemination of materially false and misleading statements and omissions and caused the Company to fail to maintain effective disclosure controls and procedures and adequate internal controls.

3. The Individual Defendants repeatedly failed to take red flags seriously and delayed the implementation of appropriate internal controls to ensure the Company operated in compliance with the law. The Individual Defendants willfully ignored, or recklessly failed to inform themselves of, the obvious problems with the Company’s internal controls, practices, and procedures, and failed to make a good faith effort to correct the problems or prevent their recurrence. As detailed herein, the Individual Defendants were on notice and/or became aware of risks that Humacyte was violating the law or was otherwise headed for a corporate trauma, but did nothing in response. The Individual Defendants had numerous opportunities to address the Company’s noncompliance and lack of reporting protocols and information controls. By failing to make a good faith effort to implement and monitor an oversight system and by consciously disregarding their duty to learn of and investigate red flags, the Individual Defendants failed to exercise due care and failed to satisfy their duty of loyalty to the Company and its stockholders.

4. In December 2023, the Company filed a Biologics License Application (“BLA”) with the Food and Drug Administration (“FDA”) to use ATEV in urgent arterial repair following extremity vascular trauma and it is not feasible to use a synthetic graft or

autologous vein. In February 2024, the FDA granted Priority Review with a Prescription Drug User Fee Act (“PDUFA”) date of August 10, 2024.

5. On August 9, 2024, after the market closed, Humacyte issued a press release announcing that the FDA “will require additional time to complete its review of its Biologic License Application (BLA) for the acellular tissue engineered vessel (ATEV) in the vascular trauma indication.” The press release disclosed in part, that, “[d]uring the course of the BLA review, the FDA has conducted inspections of our manufacturing facilities and clinical sites and has actively engaged with us in multiple discussions regarding our BLA filing[.]” On this news, the Company’s stock price declined \$1.29, or 16.4%, to close at \$6.62 per share on August 12, 2024.

6. On October 17, 2024, during market hours, the FDA released a Form 483 concerning Humacyte’s Durham, North Carolina facility, which revealed a number of violations, including “no microbial quality assurance,” “no microbial testing,” and inadequate “quality oversight.” On this news, the Company’s stock price declined \$0.95, or 16.35%, to close at \$4.86 per share on October 17, 2024.

7. During the Relevant Period, the Individual Defendants willfully or recklessly made and/or caused the Company to make to the investing public a series of materially false and misleading statements and omissions of material fact that failed to disclose, *inter alia*, that: (1) that the Company’s Durham, North Carolina facility failed to comply with good manufacturing practices, including quality assurance and microbial testing; (2) that the FDA’s review of the BLA would be delayed while Humacyte remediated these deficiencies; and (3) that, as a result, there was a substantial risk to FDA

approval of ATEV for vascular trauma; (4) that the Company failed to maintain internal controls and (5) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis. As a result of the foregoing, the Company's public statements were materially false and misleading and/or lacked a reasonable basis at all relevant times. The Individual Defendants' misrepresentations had the effect of misleading the investing public and artificially inflating the Company's stock price during the Relevant Period.

8. The Individual Defendants also failed to oversee compliance with cGMPs, quality assurance and microbial testing at Company facilities, and the FDA's review of the Company's BLAs.

9. In addition, just before the end of the Relevant Period, the Individual Defendants breached their fiduciary duties by causing Humacyte to sell its own stock at prices at artificially inflated prices due to the foregoing misrepresentations. Specifically, on October 4, 2024, Humacyte issued a press release announcing that it entered into a securities purchase agreement with an institutional investor to purchase approximately \$30.0 million worth of its common stock and warrants in a registered direct offering expected to close on October 7, 2024. The Company entered a similar agreement to sell approximately \$15.0 million worth of its common stock to an institutional investor on November 14, 2024, which closed the following day – two days before the FDA's announcement and Company stock drop.

10. Finally, while the Company's stock price was artificially inflated due to the false and misleading statements described herein, certain of the Individual Defendants

sold Company stock based on material, non-public Company information (“MNPI”). Additionally, Ayabudge LLC, an entity controlled by Board member Brady W. Dougan, who is married to CEO and President Laura Niklason, disposed of millions of shares, netting millions more in proceeds.

11. The Company has been substantially damaged as a result of the Individual Defendants’ knowing or reckless breaches of fiduciary duty and other misconduct. A federal securities class action case was filed in the United States District Court for the Middle District of North Carolina against the Company as well as a number of the Individual Defendants, exposing Humacyte to massive class-wide liability (the “Securities Class Action”).

12. Plaintiff did not make a demand on the Board because, as further detailed herein, demand would be a futile and useless act.

### **JURISDICTION AND VENUE**

13. This Court has subject matter jurisdiction pursuant to 28 U.S.C. § 1331 and Section 27 of the Securities Exchange Act of 1934 (the “Exchange Act”) over the claims asserted herein for violations of Section 14(a) of the Exchange Act (15 U.S.C. §§ 78n(a) and SEC Rule 14a-9 (17 C.F.R. §240.14a-9) promulgated thereunder.

14. This Court has supplemental jurisdiction over Plaintiff’s state law claims pursuant to 28 U.S.C. § 1367(a).

15. This action is not a collusive action designed to confer jurisdiction on a court of the United States that it would not otherwise have.

16. This Court has personal jurisdiction over each of the Defendants because each Defendant is either a corporation conducting business and maintaining operations in this District, or he or she is an individual who is a citizen of North Carolina or who has minimum contacts with this District to justify the exercise of jurisdiction over them.

17. Venue is proper in this District pursuant to Section 27(a) of the Securities Exchange Act and 28 U.S.C. §1391(b)(1), as Humacyte is headquartered within this District.

## **PARTIES**

### ***Plaintiff***

18. Plaintiff is, and has been at all relevant times, a shareholder of Humacyte.

### ***Nominal Defendant***

19. Nominal Defendant Humacyte is incorporated under the laws of Delaware with its principal executive offices located in Durham, North Carolina.

### ***The Individual Defendants***

20. Kathleen Sebelius has served as Chair of the Board since 2021. Sebelius is the Chief Executive Officer of Sebelius Resources LLC. Sebelius is a member of the Audit Committee.

21. Emery N. Brown, M.D., Ph.D. has served as a Company director since 2021. Brown is a member of the Nominating and Governance Committee.

22. Michael T. Constantino has served as a Company director since 2021. Constantino is Chairperson of the Audit Committee and a member of the Compensation Committee.

23. Brady W. Dougan has served as a Company director since 2021. The Company's 2024 proxy statement concedes Dougan is not an independent director.

24. C. Bruce Green, M.D. has served as a Company director since 2022. Green is a member of the Commercial Committee and the Nominating and Governance Committee.

25. Defendant Laura E. Niklason was the Company's founder, President, and Chief Executive Officer ("CEO") at all relevant times. Niklason has also served as a Company director since 2021. Niklason is a member of the Nominating and Governance Committee. The Company's 2024 proxy statement concedes Niklason is not an independent director.

26. Todd M. Pope has served as a Company director since 2021. Pope is Chairperson of the Compensation Committee and a member of the Commercial Committee.

27. Diane Seimetz, Ph.D. has served as a Company director since 2022. Seimetz is a member of the Commercial Committee.

28. Max Wallace, J.D. has served as a Company director since 2021. Wallace is Chairperson of the Nominating and Governance Committee and a member of the Compensation Committee.

29. Susan Windham-Bannister, Ph.D. has served as a Company director since 2021. Wallace is Chairperson of the Commercial Committee and a member of the Audit Committee.



30. Defendant Dale A. Sander was the Company's Chief Financial Officer ("CFO") at all relevant times.

31. Defendant Heather Prichard was the Company's Chief Operating Officer ("COO") at all relevant times.

32. Ayabudge LLC is an entity controlled by Board member Brady W. Dougan, who is married to CEO and President Laura Niklason. In the Company's 2024 proxy statement, Ayabudge LLC is listed under "Five Percent Holders" of Company stock. Ayabudge LLC, among other Defendants, sold Company stock at artificially inflated prices during the Relevant Period. According to the Company's 2024 proxy statement, "Dougan has sole voting and dispositive power over the shares held by Ayabudge LLC. Ayabudge LLC has pledged 6,191,140 shares to certain lenders in connection with a financing arrangement." The 2024 proxy statement states further that "[b]y virtue of these relationships, Dr. Niklason may be deemed to share beneficial ownership of the securities held of record by Mr. Dougan and Ayabudge LLC."

***Relevant Non-Parties***

33. John Bamforth has served as a Company director since July 2024.

34. Keith Anthony Jones has served as a Company director since July 2024.

**FIDUCIARY DUTIES OF THE INDIVIDUAL DEFENDANTS**

35. By reason of their positions as officers and/or directors of Humacyte, and because of their ability to control the business and corporate affairs of Humacyte, the Individual Defendants owed Humacyte and its shareholders fiduciary obligations of trust, loyalty, good faith, and due care, and were and are required to use their utmost ability to

control and manage Humacyte in a fair, just, honest, and equitable manner. The Individual Defendants were and are required to act in furtherance of the best interests of Humacyte and its shareholders so as to benefit all shareholders equally.

36. Each director and officer of the Company owes to Humacyte and its shareholders the fiduciary duty to exercise good faith and diligence in the administration of the Company and in the use and preservation of its property and assets and the highest obligation of fair dealing.

37. The Individual Defendants, because of their positions of control and authority as directors and/or officers of Humacyte, were able to and did, directly and/or indirectly, exercise control over the wrongful acts complained of herein.

38. To discharge their duties, the officers and directors of Humacyte were required to exercise reasonable and prudent supervision over the management, policies, controls, and operations of the Company.

39. Each Individual Defendant, by virtue of his or her position as a director and/or officer owed to the Company and to its shareholders the highest fiduciary duties of loyalty, good faith, and the exercise of due care and diligence in the management and administration of the affairs of the Company, as well as in the use and preservation of its property and assets. The conduct of the Individual Defendants complained of herein involves a knowing and culpable violation of their obligations as directors and/or officers of Humacyte, the absence of good faith on their part, or a reckless disregard for their duties to the Company and its shareholders that the Individual Defendants were aware or should have been aware posed a risk of serious injury to the Company.

40. As senior executive officers and directors of a publicly-traded company whose common stock was registered with the SEC pursuant to the Exchange Act and traded on the Nasdaq, the Individual Defendants had a duty to prevent and not to effect the dissemination of inaccurate and untruthful information with respect to the Company's financial condition, performance, growth, financial statements, products, management, internal controls, earnings, and present and future business prospects, including the dissemination of false and/or materially misleading information regarding the Company's business, prospects, and operations, and had a duty to cause the Company to disclose in its regulatory filings with the SEC all those facts described in this Complaint that it failed to disclose, so that the market price of the Company's common stock would be based upon truthful, accurate, and fairly presented information.

41. To discharge their duties, the officers and directors of Humacyte were required to exercise reasonable and prudent supervision over the management, policies, practices, and internal controls of the Company. By virtue of such duties, the officers and directors of Humacyte were required to, among other things:

- (a) ensure that the Company was operated in a diligent, honest, and prudent manner in accordance with the laws and regulations of Delaware and the United States, and pursuant to Humacyte's own Code of Conduct (the "Code of Conduct");
- (b) conduct the affairs of the Company in an efficient, business-like manner so as to make it possible to provide the highest quality performance of its business, to avoid wasting the Company's assets,

and to maximize the value of the Company's stock;

- (c) remain informed as to how Humacyte conducted its operations, and, upon receipt of notice or information of imprudent or unsound conditions or practices, to make reasonable inquiry in connection therewith, and to take steps to correct such conditions or practices;
- (d) establish and maintain systematic and accurate records and reports of the business and internal affairs of Humacyte and procedures for the reporting of the business and internal affairs to the Board and to periodically investigate, or cause independent investigation to be made of, said reports and records;
- (e) maintain and implement an adequate and functioning system of internal legal, financial, and management controls, such that Humacyte's operations would comply with all applicable laws and Humacyte's financial statements and regulatory filings filed with the SEC and disseminated to the public and the Company's shareholders would be accurate;
- (f) exercise reasonable control and supervision over the public statements made by the Company's officers and employees and any other reports or information that the Company was required by law to disseminate;
- (g) refrain from unduly benefiting themselves and other Company insiders at the expense of the Company; and

(h) examine and evaluate any reports of examinations, audits, or other financial information concerning the financial affairs of the Company and to make full and accurate disclosure of all material facts concerning, *inter alia*, each of the subjects and duties set forth above.

42. Each of the Individual Defendants further owed to Humacyte and the shareholders the duty of loyalty requiring that each favor Humacyte's interest and that of its shareholders over their own while conducting the affairs of the Company and refrain from using their position, influence, or knowledge of the affairs of the Company to gain personal advantage.

43. At all times relevant hereto, the Individual Defendants were the agents of each other and of Humacyte and were at all times acting within the course and scope of such agency.

44. Because of their advisory, executive, managerial, and directorial positions with Humacyte, each of the Individual Defendants had access to adverse, non-public information about the Company.

45. The Individual Defendants, because of their positions of control and authority, were able to and did, directly or indirectly, exercise control over the wrongful acts complained of herein, as well as the contents of the various public statements issued by Humacyte.

46. The Individual Defendants, because of their positions with Humacyte, possessed the power and authority to control the contents of the Company's reports to the

SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors. Each of the Individual Defendants was provided with copies of the Company's reports, presentations, and press releases alleged herein to be misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of the Individual Defendants knew that the adverse facts specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations which were being made were then materially false and/or misleading.

#### **HUMACYTE'S CODE OF CONDUCT**

47. Humacyte's Code of Conduct applies to everyone in the Company, including the Board of Directors.

48. Under the section titled, "Conflict of Interest," the Code of Conduct state that "[a] conflict of interest exists when private interests, including personal, family, social, or financial interests, interfere in any way with the performance of your responsibilities with respect to the Company."

49. Under the section titled "Public Reporting," the Code of Conduct states:

Full, fair, accurate and timely disclosure must be made in the reports and other documents that the Company files with, or submits to, the SEC and in its other public communications. Such disclosure is critical to ensure that the Company maintains its good reputation, complies with its obligations under the securities laws and meets the expectations of its stockholders.

Persons responsible for the preparation of such documents and

reports and other public communications must exercise the highest standard of care in accordance with the following guidelines:

- all accounting records, and the reports produced from such records, must comply with all applicable laws;
- all accounting records must fairly and accurately reflect the transactions or occurrences to which they relate;
- all accounting records must fairly and accurately reflect in reasonable detail the Company's assets, liabilities, revenues and expenses;
- accounting records must not contain any false or intentionally misleading entries;
- no transactions should be intentionally misclassified as to accounts, departments or accounting periods;
- all transactions must be supported by accurate documentation in reasonable detail and recorded in the proper account and in the proper accounting period;
- no information should be concealed from the internal auditors or the independent auditors; and compliance with the Company's internal control over financial reporting and disclosure controls and procedures is required.

50. Under the section titled, "Insider Trading," the Code of Conduct states:

Insider trading is unethical and illegal. Employees, officers and directors must not trade in securities of a company while in possession of material non-public information regarding that company. It is also illegal to "tip" or pass on inside information to any other person who might make an investment decision based on that information or pass the information to third parties. The Company has an Insider Trading Policy, which sets forth obligations with respect of trading in the Company's securities.

51. Under the section titled "Compliance with Laws, Rules and Regulations," the Code of Conduct states:

Compliance with both the letter and spirit of all laws, rules and regulations applicable to the Company, including any stock exchange or other organization or body that regulates the Company, is critical to our reputation and continued success. All employees, officers and directors must respect and obey the laws of the cities, states and countries in which the Company operates and avoid even the appearance of impropriety.

Employees, officers or directors who fail to comply with this Code and applicable laws will be subject to disciplinary measures, up to and including discharge from the Company.

52. In violation of the Code of Conduct, the Individual Defendants conducted little, if any, oversight of the Company's engagement in the Individual Defendants' scheme to issue materially false and misleading statements to the public and to facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty. Also, in violation of the Code of Conduct, the Individual Defendants engaged in insider trading and failed to maintain internal controls, failed to obtain waivers and/or failed to disclose obtained waivers of violating the Code of Conduct, and failed to comply with laws and regulations, conduct business in an honest and ethical manner, and properly report violations of the Code of Conduct.

#### **HUMACYTE'S AUDIT AND COMMERCIAL COMMITTEE CHARTERS**

53. Pursuant to Humacyte's Audit Committee Charter, the purpose of the Committee is to

assist the Board in fulfilling its oversight responsibilities relating to the Company's financial accounting, reporting and controls and certain key corporate governance functions of the Board. The Committee's principal functions are to (i) oversee the quality and integrity of the Company's financial statements and accounting and financial reporting processes, systems of internal control and the audits of the Company's financial



statements by the Company's independent auditors (the "Independent Auditors"), (ii) oversee the Independent Auditors' qualifications and independence and the performance of the Company's internal audit function and the Independent Auditors, (iii) provide risk management and governance oversight, and (iv) ensure the Company's compliance with legal and regulatory requirements.

54. According to the Audit Committee Charter, the principal responsibilities and duties of the Committee are to, among other things:

Review the Company's annual and quarterly financial statements prior to their public release, including any report on the Company's internal control over financial reporting and any report or opinion by the Independent Auditors, and consider whether such statements, reports and opinions are complete, consistent with information known to the Committee and reflective of appropriate accounting principles.

Review other sections of any annual or quarterly report or similar filing and any related regulatory filings, including the disclosures under "Management's Discussion and Analysis of Financial Condition and Results of Operations" to consider the accuracy and completeness of the information contained therein prior to their public release.

Oversee the integrity of accounting and financial reporting processes of the Company and its systems of internal control over financial reporting, including any significant deficiencies and material weaknesses in their design or operation.

Oversee the Company's (i) compliance with applicable laws and regulations, (ii) compliance framework and (iii) compliance program.

Oversee the investigation and follow-up (including disciplinary action) of any instances of material or significant noncompliance, including reports that involve actual or alleged violations of the Company's Code of Conduct and Ethics.

Review ongoing investigations, findings of any examinations by regulatory authorities, and the Company's responses to such investigations, findings and examinations.

Review the risk management processes established and maintained by management and the procedures in place to ensure that they are operating as intended.

Review with management the Company's major financial risk exposures and the steps management has taken to monitor such exposures, including the Company's procedures and any related policies, with respect to risk assessment and risk management.

Receive and discuss quarterly updates from management regarding the Company's risk management processes and systems of internal control.

55. According to Humacyte's Commercial Committee Charter, the purpose of the Committee is to "assist the Board on matters relating to the Company's strategy, activities, and investment in research, development, manufacturing, go-to-market strategies, pricing, sales, external innovation and business development initiatives."

56. According to the Commercial Committee Charter, the principal responsibilities and duties of the Committee are to:

1. Review the overall scientific, research and development, and external innovation strategy of the Company and report to the Board regarding such review in order to help facilitate the Board's oversight of the Company's innovation strategy and goals;
2. Review the Company's research and development pipeline and discuss opportunities for further product development or enhancements;
3. Review the competitive landscape in terms of related external scientific research, discoveries and commercial developments, and potential future innovations, as appropriate;
4. Review and consider management's prioritization decisions regarding the allocation, deployment, utilization of and investment in the Company's products, go-to-market capabilities and scientific and development assets;

5. Oversee and consider the Company's strategy relating to the commercialization of any of the Company's products approved by the Food and Drug Administration or any other government regulator;
6. Review and assess the Company's intellectual property portfolio and strategy;
7. Review and make recommendations to the Board on the Company's internal and external investments in science and technology, including external investments in R&D such as potential acquisitions, alliances, collaborations, equity investments, contracts and grants; and
8. Fulfill the Committee's responsibilities or other functions as assigned by law, the Company's certificate of incorporation or bylaws, the Board or the Company's other policies.

57. The Individual Defendants violated the Audit Committee Charter and the Commercial Committee Charter by engaging in or permitting the Company to engage in the scheme to issue materially false and misleading statements to the public, including in the Company's SEC filings, and by facilitating and disguising the Individual Defendants' violations of law, including breaches of fiduciary duty, and failing to report the same. Moreover, multiple the Individual Defendants violated the Code of Conduct by engaging in insider trading. In further violation of the Code of Conduct, the Audit Committee Charter, and the Commercial Committee Charter, the Individual Defendants failed to maintain internal controls, failed to maintain the accuracy of Company records and reports, failed to comply with applicable laws and regulations, and failed to conduct business in an honest and ethical manner.

58. In violation of the Audit Committee Charter and Commercial Committee Charter, members of the Audit Committee and Commercial Committee conducted little,

if any, oversight of Humacyte’s engagement in the Individual Defendants’ scheme to issue materially false and misleading statements to the public and to facilitate and disguise the Individual Defendants’ violations of law, including breaches of fiduciary duty.

### **SUBSTANTIVE ALLEGATIONS**

59. Humacyte and its consolidated subsidiaries engage in the development and manufacture of off-the-shelf, implantable, and bioengineered human tissues. The Company is currently engaged in engineering and manufacturing Acellular Tissue Engineered Vessel (“ATEV”), also known as “Human Acellular Vessel” (“HAV”), which is a lab-grown blood vessel implant that can act as a replacement for an injured or damaged blood vessel. The Company has not generated revenue from the sale of any products to date.

60. In December 2023, the Company filed a Biologics License Application (“BLA”) with the Food and Drug Administration (“FDA”) to use ATEV in urgent arterial repair following extremity vascular trauma and it is not feasible to use a synthetic graft or autologous vein. In February 2024, the FDA granted Priority Review with a Prescription Drug User Fee Act (“PDUFA”) date of August 10, 2024.

61. On April 29, 2024, Humacyte filed its 2024 annual proxy statement (“2024 Proxy”) with the SEC, wherein Defendants solicited shareholder votes – in advance of an annual stockholder meeting held on June 11, 2024 – in favor of three proposals, including the re-election of Defendants John P. Bamforth, Emery N. Brown, Michael T. Constantino, Keith Anthony Jones, Laura E. Niklason and Susan Windham-Bannister.

62. The 2024 Proxy stated that Humacyte had adopted a Code of Business Conduct & Ethics applicable to all representatives of Humacyte, including directors and officers.

63. The 2024 Proxy states that the “The Board does not have a standing risk management committee, but rather executes its oversight responsibility both directly and through its standing committees.” The 2024 Proxy also notes that the Board oversees “specific risk topics, including risks associated with our strategic initiatives, business plans, capital structure, commercializing our product candidates, liquidity, talent management, compliance and cybersecurity” but failed to disclose that none of the Board Committees were charged with overseeing compliance with cGMPs, quality assurance and microbial testing at Company facilities, and the FDA’s review of the Company’s BLAs.

64. The 2024 Proxy failed to disclose that the Company was beset with compliance problems that posed significant risks of harm, and that the Board lacked a system to oversee mission-critical compliance risks related to cGMPs, quality assurance and microbial testing at Company facilities, the FDA’s review of the Company’s BLAs, and related public disclosures.

65. According to the 2024 Proxy, “For 2023, our Compensation Committee determined that the cash bonus awards for our NEOs would be based on corporate and individual objectives.” Corporate objectives included ensuring “FDA acceptance of the BLA filing”, “Reaching agreement with the FDA on a BLA filing strategy”, and “Comple[ing] all necessary activities to prepare for a potential market launch of the

HAV”. Individual objections included were not specifically disclosed but the 2024 Proxy notes that they “supported meeting our corporate objectives.”

66. According to the 2024 Proxy, certain of the Individual Defendants’ compensation was tied to “FDA approval of one of Humacyte’s product candidates.”

67. The 2024 Proxy also was false and misleading in that it failed to disclose that: (1) contrary to the 2024 Proxy’s descriptions of the Board’s risk oversight function and the Audit Committee’s responsibilities, the Board and its Committees were not adequately exercising these functions, were causing or permitting the Company to issue false and misleading statements and violate FDA regulations, and thus the Defendants on the Board breached their fiduciary duties; and (2) the Defendants on the Board at that time who breached their fiduciary duties were improperly interested in increasing their unjust compensation.

68. The false and misleading elements of the 2024 Proxy were material to stockholders in voting on the Board’s proposals, particularly with respect to stockholders’ consideration of the reelection of incumbent directors and the approval of executive compensation.

69. On May 10, 2024, Humacyte issued a press release reporting its financial results for its fiscal first quarter ended March 31, 2024. The press release claimed that the Company was “on track” for commercial launch after the FDA had completed its pre-licensing inspection facilities in connection with the BLA. Specifically, the press release stated, in relevant part:

Humacyte First Quarter 2024 Financial Results and Business

Update

-Biologics License Application (BLA) for HAV™ Accepted by FDA-

-BLA Granted Priority Review for Vascular Trauma Indication; PDUFA date set for August 10, 2024-

-Raised approximately \$43 million in net proceeds from public offering of common stock-

\* \* \*

“During the first quarter of 2024, we achieved a major milestone with the acceptance by the Food and Drug Administration (FDA) of our Biologics License Application (BLA) seeking approval of the HAV in the vascular trauma indication,” said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. “The FDA’s decision to grant Priority Review sets a Prescription Drug User Fee Act (PDUFA) date of August 10, 2024, and the entire Humacyte team is working to support our planned U.S. market launch. Among our recent accomplishments is the completion of a Budget Impact Model illustrating the potential economic value of the HAV compared to current standard of care in vascular trauma. In addition, the FDA completed its Pre-Licensing Inspection of our manufacturing facilities in Durham, North Carolina as part of the BLA review process. We remain on track with our BLA review and commercial launch preparations and remain confident in the approvability of the HAV in vascular trauma.”

70. On May 10, 2024, the Company held an earnings call regarding its financial results for its fiscal first quarter ended March 31, 2024 (the “1Q24 Earnings Call”). During the 1Q24 Earnings Call, Defendant Niklason touted the Company’s strong progress on the HAV BLA submission to the FDA, including that the “FDA has completed its pre-licensing inspection of our manufacturing facilities in Durham, North Carolina as part of the BLA review process.” Defendant Niklason further assured investors that the Company “remain[s] on track with our BLA review and commercial launch preparations.”

Specifically, during the 1Q24 Earnings Call, Defendant Niklason stated, in relevant part:

I'll begin with our HAV program in vascular trauma. You'll recall that in December of 2023, we submitted our BLA to the FDA. During our last quarterly call, we discussed in detail the robust data package supporting our submission, which included positive results from our V005 Phase 2/3 clinical trial as well as real-world evidence from the treatment of wartime injuries in Ukraine under the humanitarian aid program that was supported by the FDA.

In February of 2024, the FDA accepted our BLA in vascular trauma, granting Priority Review and establishing a PDUFA goal date for action of August 10th. The FDA has completed its pre-licensing inspection of our manufacturing facilities in Durham, North Carolina as part of the BLA review process. We remain on track with our BLA review and commercial launch preparations, and we remain confident in the approvability of the HAV in vascular trauma.

71. During the 1Q24 Earnings Call, an analyst asked: “can you talk about the facility inspection with FDA? Any observations? Anything that you guys had to correct? How clean was that?” In response, the Defendant Prichard, stated in relevant part:

[W]e completed our pre-license inspection of our manufacturing facility and had a very successful outcome. And based on the outcome of inspection and all of the other FDA interactions on the whole, we remain very confident in approval of the HAV in vascular trauma. And we won't necessarily comment on any single interaction or the details, but we do feel very confident. And it was a very successful interaction that we have with the FDA, and we feel like it concluded very successfully.

72. During the 1Q24 Earnings Call, Defendant Niklason reiterated that the FDA had “already completed the inspection of our facility” and “things are tracking along exactly as we would have expected.” Defendant Niklason assured investors “[e]verything just seems to be progressing along as we would have expected” and that the Company has



“no indication that we're not on track” Specifically, Defendant Niklason stated in response to a question about interactions with the FDA, in relevant part:

Well, as with any BLA filing, part of the standard procedure is that after you file and after they accept the file, there is a lot of back and forth that they ask for clarifying. They ask clarifying questions. They ask for additional information. And that's been going on, frankly, since January. And those interactions have been going very smoothly, and we've been able to address all of the questions that they've been asking. There are also specific meetings that are part of the normal process, there's what's called a mid-cycle meeting, which we've already completed.

So I think that -- and as we mentioned, we've already completed the inspection of our facility. So things are tracking along exactly as we would have expected, given the timelines for a Priority Review. So again, we see no reason that the PDUFA date will shift. Of course, what -- exactly what the FDA does is always out of our control, but we have no indication that we're not on track. Everything just seems to be progressing along as we would have expected.

73. On May 13, 2024, the Company submitted its quarterly report for the period ended March 31, 2024 on a Form 10-Q filed with the SEC (the “1Q24 10-Q”). The 1Q24 10-Q purported to warn of the risks facing the Company, including those related to the Company’s “development of clinical and commercial manufacturing capabilities . . . to successfully manufacture our product.” Specifically, the 1Q24 10-Q stated the following, in relevant part:

[N]umerous risks and uncertainties associated with the development of our product candidates, including:

\* \* \*

- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities including the

FDA and non-U.S. regulators;

\* \* \*

- development of clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that it or its third-party manufacturers are able to successfully manufacture our product;

\* \* \*

A change in the outcome of any of these variables could lead to significant changes in the costs and timing associated with the development of our product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate being required to conduct in order to complete the clinical development of any of our product candidates, or if we experience significant delays in the enrollment or the conduct of any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

74. The 1Q24 10-Q purported to describe the relevant overview of the Company's operations and the progress of the Company's BLA for ATEV. Specifically, the 1Q24 10-Q stated in relevant part:

In September 2023, we announced positive topline results from our V005 Phase 2/3 trial in vascular trauma, and in December 2023, we filed a BLA for urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and when autologous vein use is not feasible. In February 2024, the FDA accepted the BLA filing and granted priority review and set a Prescription Drug User Fee Act date of August 10, 2024.

75. The above statements were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the Company's Durham,

North Carolina facility failed to comply with good manufacturing practices, including quality assurance and microbial testing; (2) that the FDA’s review of the BLA would be delayed while Humacyte remediated these deficiencies; and (3) that, as a result, there was a substantial risk to FDA approval of ATEV for vascular trauma; and (4) that, as a result of the foregoing, Defendants’ positive statements about the Company’s business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

76. The truth began to emerge on August 9, 2024, after the market closed, when Humacyte issued a press release announcing that the FDA “will require additional time to complete its review of its Biologic License Application (BLA) for the acellular tissue engineered vessel (ATEV) in the vascular trauma indication.” The press release disclosed in part, that, “[d]uring the course of the BLA review, the FDA has conducted inspections of our manufacturing facilities and clinical sites and has actively engaged with us in multiple discussions regarding our BLA filing[.]” Specifically, the press release stated, in relevant part:

Humacyte Announces FDA Communication of Additional Time Required to Complete Review of acellular tissue engineered vessel (ATEV™) BLA for the Treatment of Vascular Trauma

\* \* \*

Humacyte, Inc. (Nasdaq: HUMA), a clinical-stage biotechnology platform company developing universally implantable, bioengineered human tissues at commercial scale, today announced that the U.S. Food and Drug Administration (FDA) will require additional time to complete its review of its Biologic License Application (BLA) for the acellular tissue engineered vessel (ATEV) in the vascular trauma indication. The ATEV trauma program BLA was submitted to FDA in

December 2023, and the FDA granted a Priority Review in February 2024 and assigned a PDUFA date of August 10, 2024. In a phone call from FDA CBER leadership today, the Company was informed that the FDA required additional time to complete its review.

“We received a call from FDA CBER leadership this afternoon apologizing to us and stating that additional time was required for review.” said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. “FDA leadership noted that Humacyte’s ATEV is a first-in-class product, and that Priority Review had been granted, which allows only a six-month review cycle, as compared to the standard ten-month review cycle for most products. During the course of the BLA review, the FDA has conducted inspections of our manufacturing facilities and clinical sites and has actively engaged with us in multiple discussions regarding our BLA filing, including post-marketing and labeling discussions. Based on these interactions, we are confident in the approvability of the ATEV in treating vascular trauma. The FDA leadership expressed an apology for their inability to complete the review by the PDUFA date, and currently we do not yet have a revised action date.

77. On this news, the Company’s stock price declined \$1.29, or 16.4%, to close at \$6.62 per share on August 12, 2024, on unusually heavy volume.

78. On August 13, 2024, Humacyte issued a press release reporting its financial results for its fiscal second quarter ended June 30, 2024. The press release touted that the “FDA has conducted inspections of our manufacturing facilities and clinical sites and has actively engaged with us in multiple discussions regarding our BLA filing” and these interactions lead the Company to be “confident.” Specifically, the press release stated, in relevant part:

“We were surprised to be notified by the FDA that they will require additional time to complete their review of the BLA for our ATEV (acellular tissue engineered vessel) in vascular

trauma,” said Laura Niklason, M.D., Ph.D., Chief Executive Officer of Humacyte. “FDA leadership noted that Humacyte’s ATEV is a first-in-class product, and that Priority Review had been granted, which involves only a six-month review cycle, as compared to the standard ten-month review cycle for most products. During the course of the BLA review, the FDA has conducted inspections of our manufacturing facilities and clinical sites and has actively engaged with us in multiple discussions regarding our BLA filing, including post-marketing and labeling discussions. Based on these interactions, we are confident in the approvability of the ATEV in treating vascular trauma, although we currently do not yet have a revised action date.”

79. On August 13, 2024, the Company submitted its quarterly report for the period ended June 30, 2024 on a Form 10-Q filed with the SEC (the “2Q24 10-Q”). The 2Q24 10-Q purported to warn of the risks facing the Company, including the Company’s “development of clinical and commercial manufacturing capabilities . . . to successfully manufacture our product.” Specifically, the 2Q24 10-Q stated the following, in relevant part:

[N]umerous risks and uncertainties associated with the development of our product candidates, including:

\* \* \*

- the timing, receipt and terms of any marketing approvals from applicable regulatory authorities including the FDA and non-U.S. regulators;

\* \* \*

- development of clinical and commercial manufacturing capabilities or making arrangements with third-party manufacturers in order to ensure that it or its third-party manufacturers are able to successfully manufacture our product;

\* \* \*

A change in the outcome of any of these variables could lead to significant changes in the costs and timing associated with the development of our product candidates. For example, if the FDA or another regulatory authority were to require us to conduct clinical trials beyond those that we currently anticipate being required to conduct in order to complete the clinical development of any of our product candidates, or if we experience significant delays in the enrollment or the conduct of any of our clinical trials, we could be required to expend significant additional financial resources and time on the completion of clinical development.

80. The 2Q24 10-Q purported to describe the relevant overview of the Company's operations and the progress of the Company's BLA for ATEV. Specifically, the 1Q24 10-Q stated in relevant part:

We are initially using our proprietary, scientific technology platform to engineer and manufacture ATEVs. Our investigational ATEVs are designed to be easily implanted into any patient without inducing a foreign body response or leading to immune rejection. We are developing a portfolio, or "cabinet", of ATEVs with varying diameters and lengths.

\* \* \*

In September 2023, we announced positive topline results from our V005 Phase 2/3 trial in vascular trauma, and in December 2023, we filed a BLA for urgent arterial repair following extremity vascular trauma when synthetic graft is not indicated, and when autologous vein use is not feasible. In February 2024, the FDA accepted the BLA filing and granted priority review and set a Prescription Drug User Fee Act date of August 10, 2024. On August 9, 2024, the FDA informed us that it required additional time to complete its review of the BLA for the vascular trauma indication.

81. The above statements were materially false and/or misleading, and failed to disclose material adverse facts about the Company's business, operations, and prospects. Specifically, Defendants failed to disclose to investors: (1) that the Company's Durham,

North Carolina facility failed to comply with good manufacturing practices, including quality assurance and microbial testing; (2) that the FDA's review of the BLA would be delayed while Humacyte remediated these deficiencies; and (3) that, as a result, there was a substantial risk to FDA approval of ATEV for vascular trauma; (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

82. On October 17, 2024, during market hours, the FDA released a Form 483 concerning Humacyte's Durham, North Carolina facility. An FDA Form 483 is issued to firm management at the conclusion of an inspection when an investigator has observed any conditions that in their judgment may constitute violations of the Food Drug and Cosmetic Act and related Acts. The Form 483 revealed that, during an inspection performed by the FDA on April 1, 2024 through April 5, 2024, of Humacyte's facility, the FDA identified a number of violations including, among other things, references to "no microbial quality assurance," "no microbial testing," and "quality oversight is inadequate" for a number of issues. Specifically, the Form 483 stated, in relevant part:

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp.: Alifiya H. Ghadiali Telephone: 301-796-2064 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 04/01/2024 - 04/05/2024  FEI NUMBER 3014294024
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Heather Prichard, Chief Operating Officer	
FIRM NAME Humacyte Global, Inc.	STREET ADDRESS 2525 E. Highway NC 54
CITY, STATE AND ZIP CODE Durham, NC 27713	TYPE OF ESTABLISHMENT INSPECTED Drug product manufacturer
<p>THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OF YOUR FACILITY. THEY ARE INSPECTIONAL OBSERVATIONS; AND DO NOT REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YOU HAVE AN OBJECTION REGARDING AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO IMPLEMENT CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OR ACTION WITH THE FDA REPRESENTATIVE(S) DURING THE INSPECTION OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT FDA AT THE PHONE NUMBER AND ADDRESS ABOVE.</p> <p>DURING AN INSPECTION OF YOUR FIRM (S) (WE) OBSERVED:</p> <p>1. There is no microbial quality assurance of the (b) (4) used for the (b) (4). Specifically, there is no microbial testing or (b) (4) formulated using (b) (4) steps.</p> <p>2. Quality oversight is inadequate for the following issues observed:</p> <p>a. Investigating Out of Specification Results, SOP-0313-04, does not contain procedures for requesting an extension or opening a deviation if the investigation is not completed within the recommended 60 days. There were 10 out of 31 out-of-specification investigations from (b) (4) that were open for more than 100 days, with the longest being open for 710 days.</p> <p>b. The contract cleaning crew was not current with their (b) (4) cGMP Refresher Training as required by the Training Program, SOP-0315-04. Additionally, one member of the cleaning crew was not current on the GxP Cleaning Contractor Core Training "Facility Cleaning and Disinfection".</p> <p>c. A complete record for the role-based training (b) (4) was not available for an operator observed participating in (b) (4) in (b) (4) Room (b) (4).</p> <p>d. The quality review of the (b) (4) preventative maintenance of the air handling unit was approved without the required documentation in (b) (4) per Use of (b) (4) SOP-0127-01 and Preventative Maintenance, SOP-0169-04.</p>	
<p>SEE REVERSE OF THIS PAGE</p> <p><b>/S/</b></p>	<p>EMPLOYEE(S) NAME AND TITLE (Print or Type) Alifiya H. Ghadiali, Lead Consumer Safety Officer Zainab Mansaray-Storms, Consumer Safety Officer Laura Ricles, Division Director Jin Sung Hong, Biologist</p> <p>DATE ISSUED 04/05/2024</p>
FORM FDA 483 (8/08) PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS Page 1 of 1

83. On this news, the Company's stock price declined \$0.95, or 16.35%, to close at \$4.86 per share on October 17, 2024, on unusually heavy volume.

### Insider Sales

84. During the Relevant Period, while the Company's stock price was artificially inflated due to the false and misleading statements described herein, certain of the Individual Defendants sold Company stock based on material, non-public Company information ("MNPI"). These sales are detailed in the chart below:



<b>Defendant</b>	<b>Position</b>	<b>Date of Sale</b>	<b>Number of Shares</b>	<b>Average Share Price</b>	<b>Total Transaction</b>
Heather Ledbetter Prichard	COO	5/30/2024	188,886	\$8.14	\$1,537,532.04
Laura E. Niklason	CEO, Director	5/31/2024	809,786	\$7.91	\$6,405,407.26
Laura E. Niklason	CEO, Director	6/11/2024	358,630	\$7.08	\$2,539,100.40
Brady W Dougan	Director	6/12/2024	271,518	\$7.30	\$1,982,081.40
Dale A. Sander	CFO	8/27/2024	39,389	\$6.68	\$263,118.52
Brady W Dougan	Director	8/27/2024	252,676	\$6.71	\$1,695,455.96
Laura E. Niklason	CEO, Director	8/28/2024	277,090	\$6.47	\$1,792,772.30
Brady W Dougan	Director	8/29/2024	352,112	\$6.35	\$2,235,911.20
Laura E. Niklason	CEO, Director	9/9/2024	157,704	\$5.42	\$854,755.68
Kathleen Sebelius	Director	9/10/2024	5,182	\$5.40	\$27,982.80

85. Additionally, Ayabudge LLC, an entity controlled by Board member Brady W. Dougan, who is married to CEO and President Laura Niklason, disposed of millions of Humacyte shares, netting millions more in profits.

86. As directors and/or executives of the Company, these Defendants possessed

material non-public information about the Company. These Defendants took advantage of the confidential information, they possessed to secure the maximum profits for their shares before the information became public and the stock price dropped.

### **HARM TO THE COMPANY**

87. As a direct and proximate result of the Individual Defendants' misconduct outlined herein, the Company has lost and expended, and will continue to lose and expend, millions of dollars. These costs include, *inter alia*: (i) legal fees in connection with the Securities Class Action, including attorneys', accountants', experts', and investigators' fees; (ii) costs to implement measures to remedy the material weaknesses in Humacyte's internal controls over financial reporting; and (iii) substantial compensation and benefits paid to the Individual Defendants, who breached their fiduciary duties to the Company.

88. As a direct and proximate result of the Individual Defendants' misconduct and breach of fiduciary duties, the Company has also suffered and will continue to suffer a loss of reputation and goodwill, and a liar's discount regarding Humacyte's stock in the future.

### **DERIVATIVE AND DEMAND FUTILITY ALLEGATIONS**

89. Plaintiff brings this action derivatively in the right and for the benefit of the Company to redress injuries suffered and to be suffered as a direct and proximate result of the breach of fiduciary duties by the Individual Defendants.

90. Humacyte is named solely as a nominal party in this action. This is not a collusive action to confer jurisdiction on this Court that it would otherwise not have.

91. Plaintiff is a current shareholder of Humacyte and was a continuous shareholder of the Company during the period of the Individual Defendants' wrongdoing alleged herein. Plaintiff will adequately and fairly represent the interests of the Company in enforcing and prosecuting its rights and retained counsel competent and experienced in derivative litigation.

92. At the time this action was commenced, the twelve-member Board was comprised of Defendants Sebelius, Brown, Constantino, Dougan, Green, Niklason, Pope, Seimetz, Wallace, Windham-Bannister (the "Director Defendants") and non-parties Bamforth and Jones (together with the Director Defendants, the "Demand Board"). Accordingly, Plaintiff is only required to show that six members of the Demand Board cannot exercise independent objective judgment about whether to bring this action or whether to vigorously prosecute this action. As detailed below, demand is futile as to each member of the Demand Board, and if not, at least as to the ten Director Defendants.

93. Each of the Director Defendants are incapable of making an independent and disinterested decision to institute and vigorously prosecute this action, including because they face a substantial likelihood of liability, and so demand on the Board to institute this action is not necessary because such a demand would have been a futile act.

94. Each of the Director Defendants face a substantial likelihood of liability as a result of the scheme they engaged in knowingly or recklessly to make and/or cause the Company to make false and misleading statements and omissions of material facts, which renders them unable to impartially investigate the charges and decide whether to pursue action against themselves and the other perpetrators of the scheme.

95. Demand is excused as to all of the Director-Defendants because each of them faces, individually and collectively, a substantial likelihood of liability as a result of the scheme they engaged in knowingly or recklessly to make and/or cause the Company to make false and misleading statements and omissions of material facts, and as a result of their illegal insider sales and intentional or reckless approval of the stock offerings at artificially inflated prices during the Relevant Period. The Director Defendants, as alleged herein, were aware or should have been aware of the misinformation being spread by the Company and yet approved the repurchases. This renders the Director-Defendants unable to impartially investigate the charges and decide whether to pursue action against themselves and the other perpetrators of the scheme. Thus, the Director-Defendants breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile, and thus excused.

96. In complete abdication of their fiduciary duties, the Director-Defendants either knowingly or recklessly caused or permitted Humacyte to issue materially false and misleading statements. Specifically, the Director Defendants made or permitted the issuance of false statements and/or failed to disclose that: (1) that the Company's Durham, North Carolina facility failed to comply with good manufacturing practices, including quality assurance and microbial testing; (2) that the FDA's review of the BLA would be delayed while Humacyte remediated these deficiencies; and (3) that, as a result, there was a substantial risk to FDA approval of ATEV for vascular trauma; and (4) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

97. The Director Defendants also failed to establish or maintain a system to oversee mission-critical compliance risks related to cGMPs, quality assurance and microbial testing at Company facilities, the FDA's review of the Company's BLAs, and related public disclosures.

98. Moreover, the Director-Defendants caused the Company to fail to maintain internal controls. As a result of the foregoing, the Director-Defendants breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested or independent, and demand upon them is futile, and thus excused.

99. The Company concedes that Defendant Laura E. Niklason, the Company's CEO at all relevant times, lacks independence. Niklason is also a defendant in the Securities Class Action.

100. In violation of the Audit Committee Charter, members of the Audit Committee conducted little, if any, oversight of Humacyte's engagement in the Individual Defendants' scheme to issue materially false and misleading statements to the public and to facilitate and disguise the Individual Defendants' violations of law, including breaches of fiduciary duty, unjust enrichment, abuse of control, gross mismanagement, waste of corporate assets, and violations of the Exchange Act. Moreover, in further violation of the Audit Committee Charter, the Audit Committee Defendants failed to compliance and the adequacy of the Company's internal controls, including the Company's internal control over financial reporting and disclosure controls and procedures.

101. The Director Defendants, together and individually, violated and breached their fiduciary duties of candor, good faith, and loyalty. Specifically, the Director

Defendants knowingly approved and/or permitted the wrongs alleged herein and participated in efforts to conceal those wrongs. The Director Defendants authorized and/or permitted the Company to violate the law, authorized and/or permitted the issuance of various false and misleading statements, and are principal beneficiaries of the wrongdoing alleged herein. Accordingly, the Director Defendants could not fairly and fully prosecute such a suit even if they instituted it.

102. The Director Defendants either knowingly or recklessly issued or caused the Company to issue the materially false and misleading statements alleged herein. The Director Defendants knew of the falsity of the misleading statements at the time they were made. As a result of the foregoing, the Director Defendants breached their fiduciary duties, face a substantial likelihood of liability, are not disinterested, and demand upon them is futile, and thus excused.

103. As members of the Board charged with overseeing the Company's affairs, each of the Director Defendants had knowledge, or the fiduciary obligation to inform themselves, of information pertaining to the Company's core operations and the material events giving rise to these claims. Specifically, as Board members of Humacyte, the Director Defendants knew, or should have known, the material facts surrounding Humacyte's compliance with securities laws and the accuracy of its public statements.

104. Demand in this case is excused because each of the directors derive hundreds of thousands of dollars annually from the Company, control the Company, and are indebted to each other. These and other conflicts of interest have precluded the current directors from calling into question the Director Defendants' conduct or taking any remedial actions

to redress the conduct alleged herein. Accordingly, the Director Defendants are incapable of making an independent and disinterested decision to institute and vigorously prosecute this action due to their close relationship with, and indebtedness to, the Director Defendants named herein.

105. All of the Director Defendants are subject to the Company's Code of Conduct. The Code of Conduct goes well beyond the basic fiduciary duties required by applicable laws, rules, and regulations, requiring the members of the Demand Board to also adhere to Humacyte's of business conduct. The Director Defendants violated the Code of Conduct because they knowingly or recklessly allowed the Company to violate the law. All of the Director Defendants violated the Code of Conduct, including by refusing to take action to address the misconduct alleged herein. As such, the entire Demand Board faces a substantial likelihood of liability for breaching their fiduciary duties, and therefore demand upon them is futile.

106. None of the Director Defendants have taken any remedial action to investigate or redress the Company's losses and exposure due to their and the other Individual Defendants' misconduct.

107. The Director Defendants may also be protected against personal liability for their acts of mismanagement and breaches of fiduciary duty alleged herein by directors' and officers' liability insurance if they caused the Company to purchase it for their protection with corporate funds *i.e.*, monies belonging to the stockholders of Humacyte. If there is a directors' and officers' liability insurance policy covering the Director Defendants, it may contain provisions that eliminate coverage for any action brought

directly by the Company against the Director Defendants, known as, *inter alia*, the “insured-versus-insured exclusion.” As a result, if the Director Defendants were to sue themselves or certain officers of Humacyte, there would be no directors’ and officers’ insurance protection. Accordingly, the Director Defendants cannot be expected to bring such a suit. On the other hand, if the suit is brought derivatively, as this action is brought, such insurance coverage, if such an insurance policy exists, will provide a basis for the Company to effectuate a recovery. Thus, demand on the Director Defendants is futile and, therefore, excused.

108. If there is no directors’ and officers’ liability insurance, then the Director Defendants will not cause Humacyte to sue the Defendants named herein, since, if they did, they would face a large uninsured individual liability. Accordingly, demand is futile in that event as well.

109. Accordingly, a pre-suit demand on the current Board comprised of the Director Defendants is futile and excused.

### **COUNT I**

#### **Against the Director Defendants for Violations of § 14(a) of the Exchange Act, 15 U.S.C. § 78n(a) and Rule 14a-9 (17 C.F.R. §240.14a-9)**

110. Plaintiff repeats and realleges each and every allegation contained above as if fully set forth herein.

111. Section 14(a) of the Exchange Act, 15 U.S.C. § 78n(a)(1), provides that “[i]t shall be unlawful for any person, by use of the mails or by any means or instrumentality of interstate commerce or of any facility of a national securities exchange or otherwise, in



contravention of such rules and regulations as the [SEC] may prescribe as necessary or appropriate in the public interest or for the protection of investors, to solicit or to permit the use of his name to solicit any proxy or consent or authorization in respect of any security (other than an exempted security) registered pursuant to section 12 of this title [15 U.S.C. § 78l].”

112. Rule 14a-9, promulgated pursuant to § 14(a) of the Exchange Act, provides that no proxy statement shall contain “any statement which, at the time and in light of the circumstances under which it is made, is false or misleading with respect to any material fact, or which omits to state any material fact necessary in order to make the statements therein not false or misleading.” 17 C.F.R. § 240.14a-9.

113. Under the direction and watch of the Director Defendants, the 2024 Proxy failed to disclose, *inter alia*: (1) contrary to the 2024 Proxy’s descriptions of the Board’s risk oversight function and the Audit Committee’s responsibilities, the Board and its committees were not adequately exercising these functions, were causing or permitting the Company to issue false and misleading statements, and thus the Defendants on the Board breached their fiduciary duties; and (2) the Defendants on the Board at that time who breached their fiduciary duties were improperly interested in increasing their unjust compensation.

114. The 2024 Proxy further failed to disclose that the Company was violating FDA regulations and cGMPs, issuing false and misleading statements in violation of securities laws, and had failed to establish or maintain adequate internal controls. As a result, the 2024 Proxy was materially false and misleading.

115. In the exercise of reasonable care, these Defendants should have known that the statements contained in the 2024 Proxy were materially false and misleading.

116. The misrepresentations and omissions in the 2024 Proxy were material to Company stockholders in voting on the 2024 Proxy. The misrepresentations and omissions were material to Company stockholders in voting on the matters set forth for stockholder determination in the 2024 Proxy, including but not limited to the reelection of certain Director Defendants. The 2024 Proxy was an essential link in Defendants' insulation from stockholder challenge.

117. The false and misleading elements of the 2024 Proxy led to, among other things, the election of John P. Bamforth, Emery N. Brown, Michael T. Constantino, Keith Anthony Jones, Laura E. Niklason and Susan Windham-Bannister, which allowed them to continue to breach their fiduciary duties to Humacyte.

118. The Company was damaged as a result of the defendants' material misrepresentations and omissions in the 2024 Proxy.

119. No adequate remedy at law exists for Plaintiff by and on behalf of the Company.

## **COUNT II**

### **Against the Individual Defendants for Breach of Fiduciary Duties**

120. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

121. The Individual Defendants owed the Company fiduciary obligations. By reason of their fiduciary relationships, the Individual Defendants owed the Company the

highest obligation of good faith, fair dealing, loyalty, and due care.

122. The Individual Defendants violated and breached their fiduciary duties of care, loyalty, reasonable inquiry, and good faith.

123. The Individual Defendants engaged in a sustained and systematic failure to properly exercise their fiduciary duties. Among other things, the Individual Defendants breached their fiduciary duties of loyalty and good faith by allowing or permitting false and misleading statements to be disseminated in the Company's SEC filings and other disclosures and, otherwise failing to ensure that adequate internal controls were in place regarding the serious business reporting issues and deficiencies described above. These actions could not have been a good faith exercise of prudent business judgment to protect and promote the Company's corporate interests.

124. Throughout the Relevant Period, the Individual Defendants issued false and misleading statements failed to disclose material adverse facts about the Company's business and operations.

125. In breach of their fiduciary duties owed to Humacyte, the Individual Defendants willfully or recklessly made and/or caused the Company to make false and misleading statements and omissions of material fact that failed to disclose, *inter alia*, that: (1) that the Company's Durham, North Carolina facility failed to comply with good manufacturing practices, including quality assurance and microbial testing; (2) that the FDA's review of the BLA would be delayed while Humacyte remediated these deficiencies; and (3) that, as a result, there was a substantial risk to FDA approval of ATEV for vascular trauma; (4) that the Company failed to maintain adequate internal

controls; and (5) that, as a result of the foregoing, Defendants' positive statements about the Company's business, operations, and prospects were materially misleading and/or lacked a reasonable basis.

126. The Director Defendants also failed to establish or maintain a system to oversee mission-critical compliance risks related to cGMPs, quality assurance and microbial testing at Company facilities, the FDA's review of the Company's BLAs, and related public disclosures.

127. The Individual Defendants failed to correct and/or caused the Company to fail to correct the false and misleading statements and/or omissions of material fact, which renders them personally liable to the Company for breaching their fiduciary duties.

128. As a direct and proximate result of the Individual Defendants' failure to fulfill their fiduciary obligations, the Company has sustained significant damages.

129. As a result of the misconduct alleged herein, the Individual Defendants are liable to the Company. As a direct and proximate result of the Individual Defendants' breach of their fiduciary duties, the Company has suffered damage, not only monetarily, but also to its corporate image and goodwill. Such damage includes, among other things, costs incurred in defending itself in the Securities Class Action, exposing the Company to millions of dollars in potential class-wide damages in the Securities Class Action, and damage to the share price of the Company's stock, resulting in an increased cost of capital, and reputational harm.

### **COUNT III**

#### **Against the Individual Defendants for Unjust Enrichment**

130. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

131. By their wrongful acts, violations of law, and false and misleading statements and omissions of material fact that they made and/or caused to be made, the Individual Defendants were unjustly enriched at the expense of, and to the detriment of, Humacyte.

132. The Individual Defendants either benefitted financially from the improper conduct, or received bonuses, stock options, or similar compensation from Humacyte that were tied to the performance or artificially inflated valuation of Humacyte, or received compensation that was unjust in light of the Individual Defendants' bad faith conduct.

133. Plaintiff, as a shareholder and a representative of Humacyte, seeks restitution from the Individual Defendants and seeks an order from this Court disgorging all profits, benefits and other compensation procured by the Individual Defendants due to their wrongful conduct and breach of their fiduciary and contractual duties.

134. Plaintiff on behalf of Humacyte has no adequate remedy at law.

### **COUNT IV**

#### **Against the Individual Defendants for Abuse of Control**

135. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

136. The Individual Defendants misconduct alleged herein constituted an abuse

of their control over the Company, for which they are legally liable.

137. As a direct and proximate cause of the Individual Defendants' abuse of control, the Company has sustained substantial damages.

138. Plaintiff on behalf of the Company has no adequate remedy at law.

### **COUNT V**

#### **Against the Individual Defendants for Gross Mismanagement**

139. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

140. The Individual Defendants, either directly or through aiding and abetting, failed to reasonably exercise their responsibilities and fiduciary duties with regard to prudently managing the assets and business of the Company in a manner consistent with the expectations and operations of a publicly held corporation.

141. As a direct and proximate result of the Individual Defendants' gross mismanagement alleged herein, the Company has sustained and will continue to sustain substantial damages.

142. Plaintiff on behalf of the Company has no adequate remedy at law.

### **COUNT VI**

#### **Against the Individual Defendants for Waste of Corporate Assets**

143. Plaintiff incorporates by reference and realleges each and every allegation contained above, as though fully set forth herein.

144. The wrongful conduct alleged regarding the issuance of false and misleading statements was continuous, connected, and on-going throughout the time

period in issue. It resulted in continuous, connected, and ongoing harm to the Company.

145. As a result of the misconduct described above, the Individual Defendants wasted corporate assets by, *inter alia*: (i) paying and collecting excessive compensation and bonuses; and (ii) incurring potentially millions of dollars of legal liability and/or legal costs, including defending the Company and its officers against the Securities Class Action.

146. As a result of the waste of corporate assets, the Individual Defendants are liable to the Company.

147. Plaintiff on behalf Humacyte has no adequate remedy at law.

### **PRAYER FOR RELIEF**

WHEREFORE, Plaintiff demands judgment as follows:

A. Awarding money damages against all Individual Defendants, jointly and severally, for all losses and damages suffered as a result of the acts and transactions complained of herein, together with pre-judgment interest, molded in a fashion to ensure the Individual Defendants do not participate therein or benefit thereby;

B. Directing all Individual Defendants to account for all damages caused by them and all profits and special benefits and unjust enrichment they have obtained as a result of their unlawful conduct, including all salaries, bonuses, fees, stock awards, options and common stock sale proceeds, and imposing a constructive trust thereon;

C. Awarding punitive damages;

D. Awarding costs and disbursements of this action, including reasonable

attorneys' fees, accountants' and experts' fees, costs, and expenses; and

E. Granting such other and further relief as the Court deems just and proper.

**JURY DEMAND**

Plaintiff hereby demands a trial by jury.

Dated: January 7, 2025

/s/ Emily J. Beeson

Emily J. Beeson

NC State Bar No. 47567

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